

Department of State Health Services
Agenda Item for State Health Services Council
August 6, 2007

Agenda Item Title: New rules, 25 TAC, Chapter 98, Subsection A, concerning the Texas HIV State Pharmacy Assistance Program

Agenda Number: 3-n

Recommended Council Action:

☐ For Discussion Only

☒ For Discussion and Action by the Council

Background: The Health Promotions Unit, HIV/STD Comprehensive Services Branch would be responsible for implementing the Texas HIV State Pharmacy Assistance Program, which would assist low-income, HIV positive, Medicare beneficiaries, who reside in Texas, with limited out-of-pocket expenses associated with their Medicare Part D prescription drug benefit. On January 1, 2006, the Medicare Modernization Act of 2003 implemented prescription drug coverage for Medicare beneficiaries. Beneficiaries with incomes of 135% of the Federal Poverty level or less were awarded full low income subsidies that provided assistance with Medicare Part D Premiums and all out-of-pocket costs except for \$3-\$5 dispensing fees per prescription. Average out-of-pocket costs for beneficiaries who were denied the full low-income subsidies averaged \$4,000-\$6,000 per year. Many of these patients found these out-of-pocket costs impossible to pay and consequently began to stop taking their medications. Many of these clients are receiving assistance with some of their medications from the Texas HIV Medication Program (THMP). THMP's formulary is limited and only consists of 43 medications. The THMP receives federal AIDS Drug Assistance money. As a result of this, the assistance that the THMP currently provides does not count toward meeting the client's true out-of-pocket costs and therefore the client does not advance to the Medicare catastrophic coverage portion of the benefit and does not reap any savings. Additionally, the THMP does not reap savings as a result of the client not advancing to the catastrophic coverage benefit.

Implementing a Texas HIV State Pharmacy Assistance Program, and using state general revenue to pay for client's out-of-pocket prescription drug costs, will enable clients to advance to the catastrophic coverage portion of the Medicare Part D benefit. This will enable DSHS to purchase more medications for the same amount of money, and allow the client to acquire more medications, since state general revenue will count towards the client's true out-of-pocket costs and those costs are much less once the client advances to the catastrophic coverage benefit of Medicare Part D. The state general revenue that would be used to fund these out-of-pocket costs is currently a portion of the THMP's budget and the implementation of this program will not require any additional state general revenue.

Summary: The proposed new rules address: program eligibility; definitions; benefits; renewal requirements; denial, non-renewal and termination of benefits; program application procedures and processes; residency, and residency documentation, requirements; appeal procedures and exceptions; and confidentiality for the Texas HIV State Pharmacy Assistance Program.

Summary of Stakeholder Input to Date (including advisory committees): The HIV/STD Comprehensive Services Branch consulted the Texas HIV Medication Advisory Committee and placed the proposed rule amendments on the HIV/STD website for public comment.

Proposed Motion: Motion to recommend HHSC approval for publication of rules contained in agenda item # 3-n.

Agenda Item

Approved by: _____

Debra Stabeno, Assistant Commissioner

Presented by: Dwayne Haught **Title:** Manager

Program/Division: HIV Medication Program, Prevention and Preparedness Division

Contact Name/Phone: Todd Logan / 533-3098

Date Submitted

7/3/07

Title 25. HEALTH SERVICES

Part 1. DEPARTMENT OF STATE HEALTH SERVICES

Chapter 98. Texas HIV Medication Program

Subchapter A. Texas HIV State Pharmacy Assistance Program

New §§98.1 – 98.13

Proposed Preamble

The Executive Commissioner of the Health and Human Services Commission on behalf of the Department of State Health Services (department) proposes new §§98.1 - 98.13 concerning the Texas HIV State Pharmacy Assistance Program (SPAP).

BACKGROUND AND PURPOSE

The SPAP is designed to assist low income, HIV-positive Texans, who are Medicare Part D beneficiaries and have been denied Medicare's full low-income subsidy towards out-of-pocket expenses related to prescription drugs. On January 1, 2006, the Medicare Modernization Act of 2003 implemented prescription drug coverage for Medicare beneficiaries. Beneficiaries with incomes of 135% of the Federal Poverty level or less were awarded full low income subsidies that provided assistance with Medicare Part D Premiums and all out-of-pocket costs except for \$3-\$5 dispensing fees per prescription. Average out-of-pocket costs for beneficiaries who were denied the full low income subsidies averaged \$4,000-\$6,000 per year. Many of these patients found these out-of-pocket costs impossible to pay and consequently began to stop taking their medications. Many of these clients are receiving assistance with some of their medications from the Texas HIV Medication Program (THMP). THMP's formulary is limited and only consists of 43 medications. The THMP receives federal AIDS Drug Assistance money. As a result of this, the assistance that the THMP currently provides does not count toward meeting the client's true out-of-pocket costs and therefore the client does not advance to the Medicare catastrophic coverage portion of the benefit and does not reap any savings. Additionally, the THMP does not reap savings as a result of the client not advancing to the catastrophic coverage benefit.

The department carefully considered the most efficient way to wrap around the Medicare Part D prescription drug benefit for low income, HIV-positive Texans that would maximize the use of existing funds, expand buying power and reduce out-of-pocket costs for clients. The department believes these rules would best serve those purposes.

SECTION-BY-SECTION SUMMARY

New §98.1 provides the purpose of the SPAP; new §98.2 provides definitions for the new subchapter; new §98.3 limits assistance with out-of-pocket costs only associated with the Medicare Prescription drug plan that a client is currently enrolled in; new §98.4 describes the program's nondiscrimination policy; new §98.5 describes the program's eligibility criteria and renewal requirements; new §98.6 covers denial, non-renewal, and termination of benefits; new §98.7 describes the process to apply for services; new §98.8 describes the application submission process; new §98.9 describes residency, and residency documentation, requirements; new §98.10 describes the program's benefits the limitations to those benefits; new §98.11 concerns

department contracting; new §98.12 describes the program's appeal process; and new §98.13 concerns confidentiality.

FISCAL NOTE

Casey Blass, Director, Disease Prevention and Intervention Section, has determined that for each year of the first five-year period that the sections will be in effect, there will be fiscal implications to the state as a result of enforcing and administering the sections as proposed. The department is implementing and administering the program using existing resources. The clients who would be enrolled into the new SPAP are currently enrolled in the Texas HIV Medication Program (THMP) and currently receiving the program's medication services. These clients would be moved off THMP (reducing THMP expenditures) and onto the SPAP. The rules for the new SPAP have an annual client expenditure cap that is not to exceed the current average cost of providing services for a client on the THMP for 12 months. This ensures that the funds are budget neutral and that there will be no increase in overall expenditures. There would be a shift in expenditures from THMP to SPAP. It is important to note that it's anticipated that the proposed rules would increase the department's buying power, such that more medications could be bought with the same amount of money, thus increasing agency efficiency and improving benefits to our clients at the same time.

There is no anticipated adverse fiscal implications for local governments. The SPAP would allow the department to buy more medications with the same amount of money and also provide better benefits to our clients. This would reduce the health care burden on local governments.

Additionally, there would be a positive fiscal benefit for those individuals eligible for the program by virtue of the benefit provided.

SMALL AND MICRO-BUSINESS IMPACT ANALYSIS

Mr. Blass has also determined that there will be no effect on small businesses or micro-businesses required to comply with the sections as proposed. This was determined by interpretation of the proposed rules that small businesses and micro-businesses will not be required to alter their business practices in order to comply with the sections. There are no anticipated economic costs to persons who are required to comply with the sections as proposed. There is no anticipated negative impact on local employment.

PUBLIC BENEFIT

In addition, Mr. Blass has also determined that for each year of the first five years the sections are in effect, the public will benefit from adoption of the sections. The public benefit anticipated as a result of enforcing or administering the sections is a decrease in HIV/AIDS morbidity and mortality and their associated costs as a result of increasing access to medications used to treat HIV disease and its related conditions.

REGULATORY ANALYSIS

The department has determined that this proposal is not a "major environmental rule" as defined by Government Code, §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

The department has determined that the proposed rules do not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, do not constitute a taking under Government Code, §2007.043.

PUBLIC COMMENT

Comments on the proposal may be submitted to Dwayne Haught, Manager, Texas HIV Medication Program, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756-3189, (512) 533-3006, or dwayne.haught@dshs.state.tx.us. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register*.

LEGAL CERTIFICATION

The Department of State Health Services Deputy General Counsel, Linda Wiegman, certifies that the proposed rules have been reviewed by legal counsel and found to be within the state agencies' authority to adopt.

STATUTORY AUTHORITY

The new sections are authorized by Health and Safety Code, §85.003, which requires the department to act as lead agency and primary resource for AIDS and HIV policy; Health and Safety Code, §85.013, which requires the department to maximize the use of federal and private funds for HIV-related treatment; Health and Safety Code, §85.016, which allows for the adoption of rules; Health and Safety Code, §85.061, which establishes the Texas HIV Medication Program; Health and Safety Code, §85.063, which requires the department to establish procedures and eligibility guidelines for the HIV Medication Program; Health and Safety Code, §85.064, which allows the department to accept and use local, state, and federal funds and private donations to fund the program; and Government Code, §531.0055, and Health and Safety Code, §1001.075, which authorize the Executive Commissioner of the Health and Human Services Commission to adopt rules and policies necessary for the operation and provision of health and human services by the department and for the administration of Health and Safety Code, Chapter 1001.

The new sections affect the Health and Safety Code, Chapters 85 and 1001; and Government Code, Chapter 531.

Legend: (Proposed New Rules)
Regular Print = Proposed new language

§98.1. Purpose.

The purpose of this chapter is to establish the Texas HIV State Pharmacy Assistance Program. The program is designed to assist low-income, HIV-infected individuals with out-of-pocket costs associated with Medicare Part D prescription drug plans.

§98.2. Definitions.

These terms, when used in this subchapter, are defined as follows:

(1) AIDS--Acquired immune deficiency syndrome as defined by the Centers for Disease Control and Prevention.

(2) Commissioner--The Commissioner of the Department of State Health Services.

(3) Department--The Department of State Health Services.

(4) HIV--Human immunodeficiency virus infection as defined by the federal Centers for Disease Control and Prevention.

(5) Legally responsible person--A parent, managing conservator, or other person that is legally responsible for the support of a minor, a ward, or himself/herself.

(6) Minor--A person who has not reached his or her 18th birthday and who has not been emancipated by a court or who is not married or recognized as an adult by the State of Texas.

(7) Program--The Texas HIV State Pharmacy Assistance Program.

(8) Out-of-pocket costs--The co-pay, coinsurance and deductible amounts that an individual would be expected to pay when enrolled in a Medicare Part D prescription drug plan.

(9) Recipient--An individual who, under these sections, is determined by the department to be eligible for services.

(10) Texas resident--A person is presumed to be a Texas resident if that person physically resides within the geographic boundaries of the state, with a manifest intent to continue to physically reside within those boundaries. Manifest intent may be evidenced by any relevant information, including: voting records; automobile registration; Texas driver's license or other official identification; enrollment of children in a public or private school; or payment of property tax. The burden of proving intent to reside is on the person requesting assistance.

§98.3. Medication Coverage.

The program may only provide assistance with out-of-pocket costs for medications on the formulary of the Medicare Part D prescription drug plan that an individual is currently enrolled in.

§98.4. Nondiscrimination.

The department operates this program in a manner that allows full participation of individuals regardless of their race, color, national origin, age or disability. In addition and for purposes of the program, discrimination on the basis of gender or sexual orientation is prohibited.

§98.5. General Eligibility Criteria; Renewal.

(a) A person shall meet all of the following requirements to be eligible for the program:

(1) have a diagnosis of HIV disease certified by a physician licensed in the United States;

(2) be a Medicare beneficiary, enrolled in a Medicare Part D prescription drug plan, and denied the full low-income subsidy Part D assistance by Social Security (information on Medicare eligibility, Medicare Part D prescription drug plans and low income subsidy assistance can be found at <http://www.medicare.gov>);

(3) have an adjusted gross income of 200% or less of the current Federal Poverty Guidelines (see <http://www.aspe.hhs.gov/poverty/>);

(4) demonstrated to be a Texas resident as determined within this rule; and not be:

(A) incarcerated in a city, county, state, or federal jail or prison;

(B) admitted or committed to a state facility under the Texas Health and Safety Code; or

(C) eligible for assistance with Medicare Part D prescription drug plan out-of-pocket costs under any other program; and

(5) submit an application for HIV State Pharmacy Assistance Program benefits.

(b) The department may, at any time, verify the eligibility status of an enrolled recipient to determine if the recipient is continuing to meet the eligibility criteria of the program. The recipient must cooperate with the department, and furnish requested documentation to the department as directed.

(c) A recipient must renew enrollment in the program every two years according to the procedures established by the department. Recipient must demonstrate, at that time, continuing eligibility for the HIV State Pharmacy Assistance Program to the satisfaction of the department. Recipients must use the department's renewal application form (which may be obtained from the

department calling toll-free 1-800-255-1090 or writing to: Department of State Health Services, HIV/STD Comprehensive Services Branch, Texas HIV State Pharmacy Assistance Program, 1100 West 49th Street, Austin, Texas 78756-3199), and comply with all associated deadlines and requirements for accompanying documents.

§98.6. Denial, Non-Renewal, and Termination of Benefits.

A person may be denied enrollment in the program, be denied renewal in the program, and/or have enrollment in the program terminated for any of the following reasons:

- (1) failure to maintain Texas residency, or upon demand furnish evidence of such;
- (2) failure to continue to meet income requirements for eligibility or to provide income data as requested;
- (3) becoming eligible for the full Low Income Subsidy under Medicare Part D;
- (4) becoming incarcerated in a city, county, state, or federal jail or prison;
- (5) being admitted or committed to a state facility under the Texas Health and Safety Code;
- (6) the department determines the individual has made a material misstatement or misrepresentation on their application or any document required to support their application or renewal, or on submissions made to comply with §98.5(b) of this title (relating to General Eligibility Criteria; Renewal);
- (7) failure to continue premium payments under Medicare Part D;
- (8) failure to enroll in Medicare Part D benefits and apply for the Low Income Subsidy under the Medicare Prescription Drug Improvement and Modernization Act of 2003 (information on Medicare enrollment and applying for the Low Income Subsidy can be found at <http://www.medicare.gov>);
- (9) failure to notify the program of changes to permanent home address or insurance coverage;
- (10) the recipient notifies the program in writing that they no longer want to receive program benefits;
- (11) the recipient has not requested or used services during any period of six consecutive months; and/or
- (12) program funds are exhausted.

§98.7. Applications.

(a) Persons meeting the aforementioned eligibility requirements must submit a complete application for benefits to the department, on the form specified by the department, accompanied by the required supporting documentation. A complete application shall consist of all of the following:

(1) a complete Application for Services, with the original signature of the applicant, or the person legally responsible for the applicant, certifying that the statements made within the application are factual and true;

(2) documentation of current Texas residency;

(3) documentation acceptable to the department to establish the applicant's financial qualifications;

(4) verification that the applicant has been denied the Medicare Part D Full Low Income Subsidy assistance by Social Security;

(5) verification that the applicant has enrolled in a Medicare Part D Prescription Drug Plan that provides prescription services in Texas (Information on enrollment in a Medicare Part D Prescription Drug Plan and the available plans that provide services in Texas can be found at <http://www.medicare.gov>);

(6) verification that the applicant has a diagnosis of HIV disease and is under the care of a physician licensed to practice in the United States of America, who prescribes drugs for that person.

(b) Any application that does not meet all of the above requirements is considered incomplete. Incomplete applications will not be processed further, and the applicant will be contacted concerning the insufficiency of the application.

§98.8. Application Process.

(a) To request an application packet, call toll-free 1-800-255-1090 or write to: Department of State Health Services, HIV/STD Comprehensive Services Branch, Texas HIV State Pharmacy Assistance Program, 1100 West 49th Street, Austin, Texas 78756-3199.

(b) Submit completed application, along with accompanying documentation and certification forms, to: Department of State Health Services, HIV/STD Comprehensive Services Branch, Texas HIV State Pharmacy Assistance Program, 1100 West 49th Street, Austin, Texas 78756-3199.

(c) The applicant is expected to give informed consent to the department so that the program may contact a medical provider, Medicare, or Medicare prescription drug plan to verify

information contained in the application and/or to request additional supporting documentation pertaining to the application.

§98.9. Residency, and Residency Documentation, Requirements.

The applicant must present documentation of Texas residency as specified in this subchapter. Documents that may provide evidence of residency include:

(1) documents issued by the state or federal government, e.g., driver's license or identification card issued by the Texas Department of Public Safety; a motor vehicle registration or automobile registration form; a current Texas voter registration card; or a current benefit award letter (e.g., Social Security, Medicare, Medicaid, Food Stamps) displaying the applicant's Texas residential address;

(2) documents relating to the applicant's sources of income, both from employment and other benefits (e.g., a recent payroll statement, retirement pension or social security check, or disability check).

§98.10. Limitations and Benefits Provided.

(a) Benefits payable by the program to recipients are as follows:

(1) Limited Medicare Part D out-of-pocket expenses, which include deductibles, co-pays and co-insurance amounts. To qualify for this benefit, recipients:

(A) cannot be eligible for the full Low Income Subsidy from Medicare, covering full premium, deductible and co-insurance amounts;

(B) shall apply and be accepted for Medicare Part D benefits.

(2) The program will pay covered services up to a maximum annual allowable amount per recipient, based upon available funds. The annual allowable amount of covered services per recipient is not to exceed the total of the Texas HIV Medications Program's average monthly individual recipient cost for medications times 12 months (as calculated by the department).

(b) The Texas HIV State Pharmacy Assistance Program is the payor of last resort. All available third parties must be billed prior to the program.

(c) If budgetary limitations exist, the department may (at its sole discretion):

(1) restrict or categorize covered services. Categories will be prioritized based upon medical necessity, other third party eligibility and projected third party payments for the different treatment modalities, caseloads, and demands for services. Caseloads and demands for services may be based on current and/or projected data. In the event covered services must be reduced, they will be reduced in a manner that takes into consideration medical necessity and

other third party coverage. The department may change covered services by adding or deleting specific services, entire categories or by making changes proportionally across a category or categories, or by a combination of these methods; and/or

(2) establish a waiting list of eligible applicants. Appropriate information will be collected from each applicant who is placed on a waiting list. The information will be used to facilitate contacting the applicant when benefits become available and to allow efficient enrollment application processing should the budgetary limitations loosen.

§98.11. Provision of Service.

The department may contract with a claims processor to interface with Medicare Part D plans on behalf of the program.

§98.12. Appeal Procedures and Exceptions.

(a) An applicant whose application for initial benefits (or renewal application) is denied, or whose services have been terminated by the department, may appeal the program's decision. An applicant, recipient or person legally responsible for an applicant or recipient may initiate the appeal process by notifying the department's HIV/STD Comprehensive Services Branch that the person wishes to dispute the program's decision. The written notice must contain all arguments and supporting documents being put forward by the individual in question for the appeal. The notice should be addressed to the Department of State Health Services, HIV/STD Comprehensive Services Branch, 1100 West 49th Street, Austin, Texas, 78756-3199.

(b) A department review panel will hear the appeal. The panel shall consist of the Health Promotion Unit Manager; the HIV/STD Comprehensive Services Branch Manager; the Texas HIV Medication Program Manager, and the HIV/STD Comprehensive Services Medical Officer (or equivalent positions, in the event of an agency reorganization). The appellant may present the case in person before the panel, or rely on the written submissions, but in either event the issues on appeal and the arguments in support of those issues are limited to those already submitted in writing. Following review of the materials, and hearing from the individual in person (if applicable), the panel will issue a written decision. The panel's decision shall be final.

(c) The department is not required to offer an opportunity to dispute the decision to deny, non-renew or terminate if the department's actions are the result of the exhaustion of program funds.

§98.13. Confidentiality.

(a) No information that could identify an individual applicant will be released except as authorized by law and in accord with §1.501 of this title (relating to Privacy of Health Information). Applicants are advised that, in addition to the department, their physician(s), pharmacist(s), and designated Medicare Part D prescription drug plan will be aware of their diagnosis.

(b) The department may use or disclose individual health information to provide, coordinate, or manage health care or related services, as allowed by law. This includes referring the recipient to other health care resources. The department may contact a program applicant or recipient to discuss enrollment benefits, resources for treatment, or other health-related information as appropriate.

(c) An individual may request a copy of the department's privacy notice by writing to: Department of State Health Services, Privacy Officer, 1100 West 49th Street, Austin, Texas 78756. More information pertaining to the Health Insurance and Portability and Accountability Act (HIPPA) is available online from the department at the following URL: <http://www.dshs.state.tx.us/hipaa>.